IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application: Ron Wortley et al. Serial No.: 10/814,318 Filed: March 31, 2004 For: FLEXIBLE CONNECTION CATHETER TUNNELER AND METHODS FOR USING THE SAME	Confirmation No. 5172 Group Art Unit: 3734 Examiner: Bachman, Lindsey M.

Mail Stop Final
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, the undersigned, declare the following.

1. I am one of the inventors of Zawacki et al. (U.S. Patent Application No. 2004/067463).

2. I consider myself "one with ordinary skill in the art" in the medical device industry, including with experience with medical devices related to catheters. My qualifications include a B.S. in mechanical engineering and extensive experience in this industry, having worked in the catheter industry for more than 10 years. I am currently the V.P. of Research & Development for Bard Access Systems, a division of C. R. Bard.

3. I have reviewed Wilson et al. (U.S. Patent Application No. 2002/0099327) and am intimately familiar with Zawacki et al. since I am an inventor named in that application. I have

been informed that both of these references have been cited again the pending claims in the above-captioned application.

4. I understand that the claims have been rejected because the Examiner considers that Wilson et al. describe a multi-lumen catheter that is "capable of" being used as a tunneler. One with ordinary skill in the catheter art, however, would have understood that the tunneler of Wilson et al. is neither a tunneler and could not—and would not—have been used as a tunneler.

A. Wilson et al. specifically disclose in several instances that the catheter 12 is pulled through a tunnel that has already been created in the desired location of the patient. First, the Abstract notes that a subcutaneous tunnel is created and the first end of the tunnel is near the incision, and then the catheter 12 is routed through the tunnel. Second, paragraph [0007] describes that a subcutaneous tunnel is created and then the catheter tube is routed from the first end through the second end of the tunnel. And third, paragraph [0038] describes that a tunnel of 8 cm to 10 cm should be created by means of a tunneler and then the catheter 12 is gently pulled through the tunnel. In light of all of these disclosures, and given his knowledge in the art, the skilled artisan would have concluded that a tunnel is created by a tunneler before a catheter 12 of Wilson et al. is inserted in the tunnel. Thus, the skilled artisan would have concluded that the catheter 12 is not used as a tunneler.

B. Indeed, the skilled artisan would have not used the catheter 12 as a tunneler because the type of catheter used as catheter 12 is designed to remain inside a patient for 30 days or more. Thus, the catheter 12 would be designed from very soft, pliable material that is clinically safe to remain in a patient for such an extended time period. Being made of this soft, pliable material, though, would make it difficult—if not impossible—for it to be pushed into a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

5. I also understand that the claims have been rejected because the Examiner considers that Zawacki et al. describe a multi-lumen catheter (410) and a tunneler with a tip (430) containing multiple shaft members (440,450) with different lengths. One with ordinary skill in the catheter art would have understood that the structure illustrated in Zawacki et al. as 410 is only a catheter that could not—and would not—have been used as a tunneler.

A. Zawacki et al. specifically disclose that the catheter 410 is pulled through a tunnel that has already been created in the desired location of the patient. Zawacki et al. describe that the shape of the venous lumen can be transitioned from a D-shape in the proximal portion to a circular shape in the distal portion. The cross-sectional area is configured for the venous lumen is also standardized to permit all sizes of the catheter to be tunneled subcutaneously during implantation using a single size of a tunneling trocar. *See paragraph [0074] (empasis added).* In light of all of these disclosures, and given his knowledge in the art, the skilled artisan would have concluded that a tunnel is created by a tunneler before a catheter 410 of Zawacki et al. is inserted in the tunnel. Thus, the skilled artisan would have concluded that the catheter 410 of Zawacki et al. is not used as a tunneler.

B. Indeed, the skilled artisan would have not used the catheter 410 as a tunneler because the type of catheter used as catheter 410 is designed to remain inside a patient for 30 days or more. Thus, the catheter 410 would be designed from very soft, pliable material that is clinically safe to remain in a patient for such an extended time period. Being made of this soft, pliable material, though, would make it difficult—if not impossible—for it to be pushed into a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

6. That all statements are made of my own knowledge are true and all statements made on information and belief are believed to be true; and, further, that these statements were made

with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

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Kelly B. Powers Date